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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,456	05/02/2001	Marie-Francoise Rosier-Montus	3806.0505	1457
5487	7590	02/14/2007	EXAMINER	
ROSS J. OEHLER			SULLIVAN, DANIEL M	
SANOFI-AVENTIS U.S. LLC			ART UNIT	PAPER NUMBER
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SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		02/14/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/14/2007.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/846,456	ROSIER-MONTUS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 05 October 2006 and 15 November 2006.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-3,5-14,33-38 and 57-60 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1, 3, 7-9, 11, 12, 33-36 and 57-60 is/are allowed.
- 6) Claim(s) 2,5,6,10,13,14,37 and 38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

This Office Action is a reply to the Papers filed 5 October 2006 and 15 November 2006 in response to the Non-Final Office Action mailed 5 April 2006. Claims 1-3, 5-14, 23, 33-38, 57 and 58 were considered in the 5 April Office Action. Claim 23 was cancelled, claims 2, 3, 7-12, 33 and 57 were amended, and claims 59 and 60 were added in the 15 November Paper. Claims 1-3, 5-14, 33-38 and 57-60 are pending and under consideration.

### ***Response to Amendment and Arguments***

Rejection of claim 23 is rendered moot by the cancellation thereof.

### **Claim Objections**

Objection to claim 57 because the phrase "a polynucleotide which has having at least..." is grammatically incorrect is **withdrawn** in view of the claim amendments.

### **Claim Rejections - 35 USC § 101**

Claims 37 and 38 **stand rejected** under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for the reasons set forth in the 5 April Office Action at pages 3-4.

In response to the *prima facie* rejection of record, Applicant contends that even if the host cell might become integrated into a human being, the claimed host cell would not replace or include the human being and, therefore, the host cell cannot be properly said to encompass a human being.

This argument has been fully considered but is not deemed persuasive. As stated in the 5 April Office Action, “the host cell of the claims can reasonably be construed as encompassing a cell present or intended to be present in a human being, said cell becoming integrated into the human being and therefore being an inseparable part of the human itself.” (Emphasis added.) In other words, the claim is construed as encompassing a human being because the claimed invention encompasses a cell that is integral to and inseparable from a human being. Applicant acknowledges that the claim could cover a part of a human and, as that part might be inseparable from the human as a whole, the claim is considered to cover non-statutory subject matter.

Claim Rejections - 35 USC § 112

Rejection of claims 7-12, 33 and 34 under 35 U.S.C. 112, second paragraph, is **withdrawn** in view of the claim amendments.

Claim Rejections - 35 USC § 102

Rejection of claims 3 and 7-12 under 35 U.S.C. 102(b) as being anticipated by Langmann et al., claims 3 and 7-12 under 35 U.S.C. 102(e) as being anticipated by Tall, and claims 7-12 under 35 U.S.C. 102(e) as being anticipated by Hayden *et al.* is **withdrawn** in view of the claim amendments.

Claims 2, 5, 6, 13 and 14 **stand rejected** under 35 U.S.C. 102(b) as being anticipated by Langmann et al., claim 2 **stands rejected** under 35 U.S.C. 102(b) as being anticipated by Auffray et al., claims 2, 6, 13 and 14 **stand rejected** under 35 U.S.C. 102(e) as being anticipated

by Tall U.S. Patent No. 6,773,893 B1, and claims 2, 5, 6 and 13 **stand rejected** under 35 U.S.C. 102(e) as being anticipated by Hayden *et al.* U.S. Patent No. 6,617,122 B1. These rejections are maintained for the reasons set forth in the 5 April Office Action at pages 7-10 and herein below in the response to Applicant's arguments.

In response to the *prima facie* rejections of record, Applicant has amended claim 2 to recite "An isolated nucleic acid comprising a polynucleotide of the entire sequence of SEQ ID No. 2..." Applicant contends that the claims are free of the art because they have been amended to recite larger molecules than those disclosed in the art.

This argument has been fully considered but is not deemed persuasive. According to the broadest reasonable interpretation of the claims, "a polynucleotide of the entire sequence of SEQ ID No. 2" encompasses any polynucleotide of that sequence. The claims, as written, do not require that the nucleic acid of the claims comprise the entirety of SEQ ID NO: 2. If it is Applicant's intention that the claims comprise the entire SEQ ID NO: 2 sequence, the following claim amendment is suggested:

2. (Currently Amended) An isolated nucleic acid comprising a polynucleotide of the entire sequence of SEQ ID No. 2, or the entire complement of SEQ ID No. 2.

***New Grounds Necessitated by Amendment***

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite in reciting, "ranging from nucleotide 1 at position -1". It is unclear how the nucleotide at 1 can also be at position -1. It appears that the phrase "at position -1" should have been deleted from the claim when the claim was amended to recite "from nucleotide 1".

***Allowable Subject Matter***

Claims 1, 3, 7-9, 11, 12, 33-36 and 57-60 are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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Primary Examiner  
Art Unit 1636